VALIDATION RESULTS FOR METHOD NO. Covance Harrogate 2001-042-D2					
		MEAN	RELATIVE STD. DEV.(%)	RANGE	SEE (conc)
ANALYTE	Nicotine				
MATRIX	Human urine				
DATE	10-Aug-01				
LLOQ		1.0 ng/mL. Accuracy 112.0%. RSD 6.9%			
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units)					
(SEE = S.D./SQRT (# of determinations))					
	2 ng/mL	Low QC			0.089
	400 ng/mL	Med QC			8.158
	750 ng/mL	High QC			8.942
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quatradtic, etc.)	Linear				
Slope (mean)	0.0528				
Intercept (mean)	0.0200				
Other (mean regression value)	0.9984(1/x weighted)				
RECOVERY (as a %)					
High QC in (matrix)=	750 ng/mL	37.9%			
Med QC in (matrix)=	400 ng/mL	44.9%			
Low QC in (matrix)=	2 ng/mL	75.8%			
Results with different sample amounts (results of QC evaluations) intra-assay					
LLOQ QC=	1 ng/mL	1.12	6.90%	1.03-1.22	0.031
Low QC=	2 ng/mL	2.16	9.80%	1.82-2.45	0.087
Med QC=	400 ng/mL	379.00	6.50%	365.80-413.79	10.007
High QC=	750 ng/mL	677.27	3.30%	642.32-700.91	9.259
Results with different sample amounts (results of QC evaluations) inter-assay					
LLOQ QC=	n/a	n/a	n/a	n/a	n/a
Low QC=	2 ng/mL	2.03	10.80%	1.53-2.45	0.089
Med QC=	400 ng/mL	361.19	5.50%	332.42-413.79	8.158
High QC=	750 ng/mL	666.36	3.30%	627.04-700.91	8.942
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)		9.1% maximum			
b) Freeze/thaw (+/-% /3 cycles)		2.0% maximum			
c) Injector (+/- %/24 hrs)	Refrigerated 68 hrs	4.5% maximum			

PM3006635880

Source: https://www.industrydocuments.ucsf.edu/docs/lqcj0001